

K960902

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5- 510(k) SUMMARY as required by 807.92 (c)

Submitter's name EUREDUC

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Device Trade name: EUREDUC TP03

Device common name: Pneumatic Drainage System

Classification name: Sleeve Limb Compressible 74JOW CFR Section 870 58 00

Predicate device name: JOBST EXTREMITY PUMP(R) SYSTEM 7500

Predicate device 510(k): K882683

EUREDUC TP03 is comprised of:

- a pneumatic unit in a plastic casing with :
 - a microprocessor controlled pump;
 - a control panel
- a range of garments connectable to the unit:
 - leg boots;
 - arm sleeves;

The EUREDUC TP03 is intended for :

- Lymphedema of lower extremities; post surgical or congenital ;
- Postmastectomy lymphedema ;
- Dysfunction of the muscle pump ;
- Pre, post phases of surgery.

... / ...

Compared technical characteristics and performances (from attached labeling)

DEVICE NAME	JOBST EXTREMITY PUMP (R)	EUREDUC TP03
DEVICE 510(k)	K8826 83	NA
PRESSURE RANGE	30 to 100 mm Hg	15 to 99 mm Hg
TREATMENT CYCLE	200 s	Up to 37 s
TREATMENT SESSION	NA	30 mn
POWER	15 Watts	24 Watts
SLEEVES: No OF COMPARTMENTS	Up to 3	Up to 3

The EUREDUC TP03 has similare technical characteristics and performances, identical indications and contraindications to the JOBST EXTREMITY PUMP(R).

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